UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

CUREVAC SE (f/k/a CUREVAC AG) and CUREVAC MANUFACTURING GMBH,

Plaintiffs,

v. **Civil Action No. 2:23-cv-222**

BIONTECH SE, BIONTECH MANUFACTURING GMBH, and PFIZER, INC.,

Defendants.

OPINION AND ORDER

This matter is before the court on one motion by Plaintiffs CureVac SE and CureVac Manufacturing GMBH ("CureVac") and three motions by Defendants BioNTech SE, BioNTech Manufacturing GMBH, and Pfizer, Inc. ("BioNTech"),[1] all involving expert witness testimony regarding the TFF Patent family. In its Motion to Exclude Testimony from Dr. Zydney, BioNTech seeks to exclude Dr. Zydney's expert testimony based on "legally erroneous claim construction" that narrows the meaning of the phrase "TFF membrane cassette." (ECF No. 471, at 1). In its Motion in Limine No. 13, BioNTech requests that the court preclude Dr. Zydney from providing "opinions to the jury based on incorrect claim construction." (ECF No. 609, at 1). Lastly, in its related Motion in Limine No. 6, BioNTech seeks to preclude CureVac from introducing or discussing a "new alleged infringement document concerning the TFF Patents," cited by CureVac

[1] The court will address all four motions in the following order: BioNTech's Motion to Exclude Testimony from Andrew Zydney, Ph.D., (ECF No. 470), BioNTech's Motion in Limine No. 13, (ECF No. 608), BioNTech's Motion in Limine No. 6, (ECF No. 587), and CureVac's Motion to Exclude Expert Testimony of Anurag S. Rathore, Ph.D., (ECF No. 503). For clarity, the court has shortened the title of each motion.

for the first time in its opposition to the above Daubert motion. (ECF No. 589, at 1-2) (sealed version).

In its Motion to Exclude Testimony from Dr. Rathore, CureVac seeks to exclude Dr. Rathore's expert testimony regarding obviousness because he fails to identify a specific combination of prior art references supporting those opinions and instead relies on "general knowledge" of a person of ordinary skill in the art ("POSA"). (ECF No. 491-31, at 1) (sealed version). As explained below, the court GRANTS BioNTech's Motion to Exclude Testimony from Dr. Zydney, (ECF No. 470), GRANTS BioNTech's Motion in Limine No. 13, (ECF No. 608), DENIES BioNTech's Motion in Limine No. 6, (ECF No. 587), and DENIES CureVac's Motion to Exclude Testimony from Dr. Rathore, (ECF No. 503).

I. BACKGROUND

A. The TFF Patents.

CureVac asserts infringement of seven U.S. patents divided among four patent families. The four families each derive from applications with varying priority dates, and cover different technology alleged to be practiced by the BioNTech COVID vaccine Comirnaty®. Two patents (U.S. Patent Nos. 10,760,070 and 11,667,910) are directed to methods for purifying nucleic acids—specifically linearized DNA and mRNA using a process known as Tangential Flow Filtration (the "TFF Patents"). CureVac's Opp'n Defs.' Mot. Exclude Expert Test. of Andrew L. Zydney, Ph.D. ("CureVac's Zydney Opp'n.") (ECF No. 549-22, at 1) (sealed version). The TFF Patents both claim the same invention date of May 29, 2015, and have the same named inventors and share a common specification. Mem. Supp. Mot. Exclude Test. from Andrew Zydney ("BioNTech's Zydney Mem.") (ECF No. 471, at 3). The TFF Patents provide that "TFF may be

carried out using any suitable filter membrane. For example, TFF may be carried out using a TFF hollow fibre membrane or a TFF membrane cassette." Ex. 5 (ECF No. 106-5, at 21:1-3).

B. Dr. Zydney's Expert Report.

CureVac designated Andrew Zydney, Ph.D., to opine on the TFF Patents. On August 30, 2024, Dr. Zydney produced his opening report. See Ex. 8 (ECF No. 473-2) (sealed version). In his opening report, Dr. Zydney stated that "the words in the claims discussed in this Report would have had plain and ordinary meanings to a POSA," and he opined that "the accused process of making Comirnaty® used a tangential flow filtration membrane cassette." Id. ¶¶ 100, 108-15.

On October 4, 2024, Dr. Zydney served a rebuttal report and responded to Dr. Rathore's opinions that the TFF Patent claims are invalid over prior art, including "commercially available TFF membrane cassettes that were sold commercially for the same purpose that CureVac now claims as its invention." BioNTech's Zydney Mem. (ECF No. 471, at 6-7) (citing Ex. C (ECF No. 441-3, §§ IX-XII) (sealed version)). In his rebuttal report, Dr. Zydney argued:

> The Rathore Report does not acknowledge that the membrane cassettes specified for use in the inventions claimed in the '070 and '910 patents have screens that hold apart the membrane sheets, and do not encompass cassettes lacking screens—viz., cassettes designed for open channel flow. None of the exemplary membrane devices identified at column 21, lines 35-43, of the common specification lacks a screen, as the inventors refer to those devices as TFF membrane cassettes.

Ex. G (ECF No. 441-6, ¶ 190) (sealed version). Dr. Zydney then used his construction of "TFF membrane cassette"—i.e., a membrane cassette with screens that hold apart the membrane sheets—to distinguish prior art discussing the use of "TFF membrane cassettes" that do not use a screen. See id. ¶¶ 72-75, 80-81, 180, 183, 190-91, 200-01 (discussing how the '148 patent does not mention "screened channel devices"); id. ¶¶ 320, 321-23, 328-29, 338, 503-06, 509, 516 (discussing how the Shire prior art's disclosure of a "TFF unit operation is not a disclosure of all its potential common configurations"); id. ¶¶ 466-68 (distinguishing GSK publication because a

screened membrane cassette cannot offer suitable sheer rates); see also id. ¶¶ 272-75, 284, 290, 308, 320, 321-23, 328-29, 338, 349, 370, 394, 437, 466-68. Dr. Zydney also opined that a POSA in 2015 would have preferred to use a hollow fiber membrane cassette, and that biopharmaceutical companies "taught against" the use of screened TFF membrane cassettes. Id. §§ VIII.D, VIII.E, VIII.F. Ultimately, Dr. Zydney opines that a POSA in 2015 would have considered a TFF membrane cassette with a screen "unusable" for ultrafiltration or diafiltration of RNA or DNA because it would result in higher shear stresses that would likely destroy the RNA or DNA. Id. at ¶ 97.

C. Dr. Rathore's Expert Reports.

BioNTech designated Anurag S. Rathore, Ph.D., to opine on the TFF Patents. On August 30, 2024, Dr. Rathore produced his opening report. See Ex. 3 (ECF No. 491-32) (sealed version). In his opening report, Dr. Rathore provides several opinions and theories as to why the claims of the TFF Patents are invalid as anticipated or obvious over the prior art. See id. ¶¶ 103-592. In several of his obviousness opinions, Dr. Rathore references prior art, discusses the teachings of the reference, and then opines that when combined with the general knowledge of a POSA, the prior art renders the claimed inventions obvious to a POSA. See Mem. Supp. CureVac's Mot. Exclude Test. of Anurag S. Rathore, Ph.D. ("CureVac's Rathore Mem.") (ECF No. 491-31, at 3) (sealed version); Defs.' Mem. Opp'n Pls.' Mot. Exclude Test. from Anurag Rathore ("BioNTech's Rathore Opp'n") (ECF No. 544, at 5-6) (sealed version). Dr. Rathore's explanation of the state of the art in 2015 cites prior art references. See Ex. 3 (ECF No. 491-32, §§ X.A, XII.A).

Specifically, Dr. Rathore opines that "as of May 29, 2015, a POSA would have known that TFF was a cost- and time-efficient method, used successfully as a standard procedure in the biotechnology and pharmaceutical industries for the concentration and diafiltration of nucleic

acids." BioNTech's Rathore Opp'n (ECF No. 544, at 5) (citing Ex. 3 (ECF No. 491-32, §§ VI.A, VIII, X.A, XII.A)). He also opines that TFF "was already an industry standard tool, and a POSA would have been aware that many companies commercially sold TFF devices and filters and promoted them for biopharmaceutical applications." Id. at 6 (citing Ex. 3 (ECF No. 491-32, §§ X.A, XII.A)).

On October 25, 2024, Dr. Rathore produced his rebuttal report, Ex. I (ECF No. 441-8) (sealed version), responding to Dr. Zydney's opinions about the state of the relevant art and the general knowledge of the POSA, Ex. 6 (ECF No. 491-35, ¶¶ 68, 83-92, 96) (sealed version). Dr. Rathore further explained the state of the art before the TFF Patents, pointing to various brochures, written materials, and other studies that suggested that a POSA would be familiar with TFF devices and filters. Ex. I (ECF No. 441-8, ¶¶ 41-44, 50-57).

On August 30, 2024, Dr. Zydney also produced his opening report on infringement in support of CureVac's damages claim. Ex. 5 (491-34) (sealed version). In that report, Dr. Zydney opined that he was unaware of any acceptable and available noninfringing alternatives, stating that he could not imagine how BioNTech could have made enough drug substance to meet the market demand without using the TFF Patents. Id. ¶¶ 227-28.

On October 4, 2024, Dr. Rathore produced his rebuttal report on noninfringement, and outlined how BioNTech could have produced enough drug product without using TFF membrane cassettes. Ex. 4 (ECF No. 491-33, § VII) (sealed version). He explained how BioNTech could have instead used a hollow fiber filter, another TFF filter also used for filtering RNA, opining that "it would have been quick and inexpensive to switch [from membrane cassettes] to a TFF hollow fiber filter." Id. ¶ 64. He opined that the change would have taken less than two months to complete. Id. In supporting these opinions, Dr. Rathore relied on his expertise, documentary

evidence, research produced from the development of Comirnaty®, FDA submissions, and sworn testimony from Dr. Andreas Kuhn and Dr. Ranga Godavarti—two individuals directly involved in the Comirnaty® manufacturing process. Id. § VII.

II. STANDARD OF REVIEW

In determining the admissibility of expert witness testimony, Rule 702 of the Federal Rules of Evidence governs. United States v. Wilson, 484 F.3d 267, 274-75 (4th Cir. 2007). Under the Rule:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. In other words, expert testimony is admissible under Rule 702 "if it concerns (1) scientific, technical, or other specialized knowledge that (2) will aid the jury or other trier of fact to understand or resolve a fact at issue." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 260 (4th Cir. 1999) (citing Daubert, 509 U.S. at 592).

The first prong requires the court to examine "whether the reasoning or methodology underlying the expert's proffered opinion is reliable" and the second prong asks the court to analyze "whether the opinion is relevant to the facts at issue." Id.; see also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) ("[T]he Federal Rules of Evidence 'assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.'" (quoting Daubert, 509 U.S. at 597)); Oglesby v. General Motors Corp., 190

F.3d 244, 249-50 (4th Cir. 1999) ("[A] district judge, considering a proffer of expert testimony under Federal Rule of Evidence 702—whether based on scientific, technical, or other knowledge—must, in determining its admissibility, ensure that the evidence is 'not only relevant, but reliable'" (quoting Daubert, 509 U.S. at 589)). That is, "a reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." Oglesby, 190 F.3d at 250 (citing Daubert, 509 U.S. at 590, 592-93). "The proponent of the testimony must establish its admissibility by a preponderance of proof." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing Daubert, 509 U.S. at 592 n.10).

Thus, the District Court serves as a gatekeeper to assess whether the proffered evidence is reliable and relevant. Kumho Tire Co., 526 U.S. at 141. But the gatekeeper function does not require that the Court "determine that the proffered expert testimony is irrefutable or certainly correct" because expert testimony is "subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" United States v. Moreland, 437 F.3d 424, 431 (4th Cir. 2006) (quoting Daubert, 509 U.S. at 596). There is no "mechanistic test for determining the reliability of an expert's proffered testimony; on the contrary, 'the test of reliability is flexible and the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination.'" Peters-Martin v. Navistar Int. Trans. Corp., 410 F. App'x 612, 617 (4th Cir. 2011) (quoting Wilson, 484 F.3d at 274) (internal citations and quotations omitted).

III. ANALYSIS

A. Dr. Zydney Cannot Limit the Phrase "TFF Membrane Cassettes" Only to TFF Membrane Cassettes with Screens.

In BioNTech's Motion to Exclude Testimony from Andrew L. Zydney, Ph.D., (ECF No. 470), BioNTech explains that in his expert report, Dr. Zydney limits claims involving the phrase "TFF membrane cassette," restricting the phrase to TFF membrane cassettes using a screen. BioNTech's Zydney Mem. (ECF No. 471, at 1-2). BioNTech claims that Dr. Zydney's narrow construction of the term "TFF membrane cassette" is unreliable and inadmissible because (1) Dr. Zydney's lexicographic claim construction fails under Markman standards, and (2) Dr. Zydney cannot testify about a new limiting construction raised by CureVac for the first time in a rebuttal expert report without the court's permission. Id. at 2.

As to the first argument, BioNTech argues that when an expert's opinion is "'based on an incorrect understanding of the claim,' the Court should disregard that opinion" as irrelevant. Id. at 9, 16-17 (citing Cordis Corp. v. Bos. Sci. Corp., 658 F.3d 1347, 1357 (Fed. Cir. 2011)). BioNTech claims that Dr. Zydney's claim construction fails under Markman standards because the specification fails to provide a clear disclaimer of TFF membranes without screens. Id. at 11. BioNTech points out that the specification describes the use of TFF membrane cassettes with or without screens, and that Dr. Zydney's claim construction conflicts with Example 13 and other aspects of the specification. Id. at 13-15. As to the second argument, BioNTech claims that Dr. Zydney's testimony distinguishing the claims from the prior art that uses TFF membrane cassettes without screens would confuse the jury because the claims are not limited to TFF membrane cassettes with screens. Id. at 16. BioNTech also asserts that CureVac should have raised the issue during the claim construction phase and have consequently waived its right to raise the issue now. Id. at 19.

CureVac opposed BioNTech's motion, arguing that Dr. Zydney "nowhere offers a claim construction opinion based on lexicography (or disavowal)." CureVac's Zydney Opp'n (ECF No. 549-22, at 10). Instead, CureVac claims that Dr. Zydney relied on the plain and ordinary meaning of "TFF membrane cassette" in the specification of the TFF Patents. Id. at 6-7, 10. Further, CureVac claims that Dr. Rathore interpreted "membrane cassette" broadly to encompass any TFF device, to which Dr. Zydney should be entitled to respond. Id. at 8. CureVac also asserts that it did not waive its arguments about the meaning of "TFF membrane cassette," attributing Dr. Zydney's new characterization of "TFF membrane cassettes" to Dr. Rathore's "belated" and "impermissibly broad" construction. Id. at 13. CureVac also takes issue with BioNTech's reliance on Example 13, arguing that because Example 13 "describes a different invention that the Patent Office did not examine during prosecution of the TFF Patents," it cannot change the meaning of "TFF membrane cassette." Id. at 10.

In its reply, BioNTech again asserts that Dr. Zydney presented a lexicography argument: "that 'TFF membrane cassette' in the claim should mean 'TFF membrane cassette with a screen.'" Defs.' Mem. Resp. Pls.' Opp'n Exclude Test. from Andrew Zydney ("BioNTech's Zydney Reply") (ECF No. 663, at 1). BioNTech alleges that CureVac cannot prove "any clear disavowal" to limit the claim scope, id. at 2, that Dr. Zydney did not apply the plain and ordinary meaning of "TFF membrane cassette," id. at 3, and, therefore, cannot present Dr. Zydney's claim construction argument to the jury, id. at 7-9.

In BioNTech's related Motion in Limine No. 13, BioNTech requests that if the court grants its Motion to Exclude Testimony from Dr. Zydney, then "Dr. Zydney should be precluded from providing opinions to the jury that are based on incorrect claim construction." Mem. Supp. BioNTech & Pfizer's Mot. in Limine No. 13 to Exclude Dr. Zydney's Opinions Assuming an

Incorrect Claim Construction ("BioNTech's Second Zydney Mem.") (ECF No. 609, at 1). BioNTech relies on the same legal standards and arguments as set forth in its earlier motion, but asks the court for more specific relief, arguing that the court exclude (1) Dr. Zydney's framing of the "state of relevant art" as teaching away from the use of screened cassettes, and (2) Dr. Zydney's attempts to distinguish prior art on the basis that the prior art did not teach the use of a screened membrane cassette. Id. at 3-4.

CureVac responded, reasserting all arguments made in its opposition to BioNTech's earlier motion. CureVac's Opp'n to Defs.' Mot. Limine No. 13 ("CureVac's Second Zydney Opp'n") (ECF No. 721, at 1). CureVac asserts that if the court granted BioNTech's earlier motion, "the relief should be limited to excluding Dr. Zydney's testimony where he distinguishes prior art references specifically on the basis that they do not refer to screened cassettes." Id. CureVac also points out that the relief BioNTech requests appears much broader, referring to sections and paragraphs of Dr. Zydney's report that do not address the issue of screened cassettes. Id.

Below, the court considers the parties' arguments on BioNTech's Motion to Exclude Testimony from Dr. Zydney, (ECF No. 470), and BioNTech's Motion in Limine No. 13, (ECF No. 608).

1. Waiver of the Claim Construction Argument.

CureVac waived its claim construction argument regarding "TFF membrane cassette." Courts have discretion in deciding whether to find a party waived its opportunity to raise claim construction related concerns. See, e.g., Daedalus Blue, LLC v. Microstrategy Inc., No. 2:20-cv-551, 2023 WL 5941736, at *13 (E.D. Va. Sept. 12, 2023) (quoting Cioffi v. Google, Inc., No. 2:13-cv-103, 2017 WL 275386, at *5 n.2 (E.D. Tex. Jan. 9, 2017) ("The court has ample grounds to find that Google waived its claim construction arguments . . . but the [c]ourt declines to find waiver

at this stage.")); Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols., P.C., 482 F.3d 1347, 1356 (Fed. Cir. 2007) ("The district court found that ACS waived any argument with respect to this term by failing to raise it during the claim construction phase. We agree. Since ACS has not preserved this argument before the district court, we do not reach it here."). In Daedalus, the need to seek further claim construction arose from a newly asserted infringement theory in an opposing expert report, raised after claim construction and fact discovery. 2023 WL 5941736, at *14. Accordingly, the court declined to find that the defendant waived its argument because "[f]inding waiver under such circumstances would essentially amount to punishing [d]efendant for circumstances outside of its control." Id.

Here, no circumstances outside CureVac's control arose after Markman that presented the need for further claim construction.[2] BioNTech raised its invalidity arguments for the TFF Patents—and CureVac responded to those invalidity claims—before Markman proceedings. See Ex. 7 (ECF No. 472-7, at 56-57, 61-63, 66, 67). CureVac had the opportunity to raise its claim construction argument regarding "TFF membrane cassette" during Markman, and it failed to do so. See Scheduling Order (ECF No. 124, at 3-4) (describing the period from January to April 2024 in which parties proceeded with claim construction exchanges); Joint Claim Construction Chart Ex. A (ECF No. 298-1, at 1). Thus, the court finds that CureVac waived its claim construction argument regarding "TFF membrane cassette."

[2] CureVac expresses concern with, what it describes as, Dr. Rathore's "broad reading" of cassette, claiming that it "would encompass essentially any TFF device." CureVac's Zydney Opp'n. (ECF No. 549-22, at 8, 13). To the extent CureVac argues that Dr. Rathore's interpretation of "TFF membrane cassette" serves as a circumstance outside of CureVac's control, the court is not persuaded. As discussed below, Claim 1 of the '070 Patent refers only to "TFF membrane cassette," and the Patents' specification contemplates both TFF membrane cassettes with and without screens. Certainly, CureVac was aware of its own Patents' language prior to Markman, and could have sought that construction adopted by Dr. Zydney during these proceedings.

2. CureVac's Plain and Ordinary Meaning and Lexicographic Arguments.

Notwithstanding CureVac's waiver of the claim construction argument, CureVac's plain and ordinary meaning and lexicographic arguments also fail. "There is a heavy presumption that claim terms are to be given their ordinary and customary meaning." Aventis Pharm. Inc. v. Amino Chems. Ltd., 715 F.3d 1363, 1373 (Fed. Cir. 2013). Plain and ordinary meaning is the meaning one of ordinary skill in the art would ascribe to a term when read in the context of the claim, specification, and prosecution history. See Phillips v. AWH Corp., 415 F.3d 1303, 1313-14 (Fed. Cir. 2005) (en banc). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2). When the patentee disavows the full scope of a claim term either in the specification or during prosecution." Thorner v. Sony Computer Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term." Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (quotation marks and citation omitted).

"[S]pecification explanations may lead one of ordinary skill to interpret a claim term more narrowly than its plain meaning suggests." Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed. Cir. 2008). But for a specification to suggest such a narrowing of the claim language, it must include "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope" suggested by the plain and ordinary meaning. Thorner, 669 F.3d at 1366; Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002); see Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004) ("Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is

entitled to the full scope of its claim language."); see also Computer Docking Station Corp., 519 F.3d at 1374 ("For example, repeated and definitive remarks in the written description could restrict a claim limitation to a particular structure.").

CureVac asserts that Dr. Zydney is applying the plain and ordinary meaning of the term. However, Claim 1 of the '070 Patent specifies: "diafiltering and/or concentrating and/or purifying the linearization reaction compromising linearized plasmid DNA by one or more steps of tangential flow filtration [(]TFF) using a TFF membrane cassette." Am. Countercl. Ex. 5 (ECF No. 106-5, at 57:47-64). Claim 1 makes no reference to screens. See M2M Sols. LLC v. Amazon.com, Inc., Nos. 2022-1122, 2022-1124, 2023 WL 2154964, at *3 (Fed. Cir. Feb. 22, 2023) ("[T]he most important tool in determining the meaning of a claim is the claim language itself.").

Moreover, the TFF Patents' specification contemplates TFF membrane cassettes with and without screens. See Phillips, 415 F.3d at 1315 (stating that the specification "is the single best guide to the meaning of the disputed term."). For example, the specification cites both the "Omega Centramate"—a cassette with a screen—and the "Vivaflow 50"—a cassette without a screen. Ex. 5 (ECF No. 106-5, at 21:37, 38:20-45, 47:35-52:67). Further, Example 13 in the specification—described as the "Complete Process" for filtering using TFF—uses the "Vivaflow 50 filter cassette." Id. 47:36-52:67. Thus, while "TFF membrane cassette" could mean a "TFF membrane cassette" with a screen, under the claim language and specification, it does not necessarily follow that "TFF membrane cassette" only means "TFF membrane cassette" with a screen.

CureVac appears to agree that Dr. Zydney "nowhere offers a claim construction opinion based on lexicography (or disavowal)." CureVac's Zydney Opp'n (ECF No. 549-22, at 10). And yet, his report clearly states:

> The Rathore Report does not acknowledge that the membrane cassettes specified for use in the inventions claimed in the '070 and '910 patents have screens that hold apart the membrane sheets, and do not encompass cassettes lacking screens—viz., cassettes designed for open channel flow. None of the exemplary membrane devices identified at column 21, lines 35-43, of the common specification lacks a screen, as the inventors refer to those devices as TFF membrane cassettes.

Ex. G (ECF No. 441-6, ¶ 190) (emphasis added). As mentioned above, "To act as its own lexicographer" a patentee must (1) "clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning," and (2) "must clearly express an intent to redefine the term." Kyocera Senco Indus. Tools Inc., 22 F.4th at 1378 (quotation marks and citation omitted). Despite Dr. Zydney's attempt at redefining the phrase, CureVac explicitly argues that Dr. Zydney does not make a lexicographic argument, claiming that the plain and ordinary meaning of "TFF membrane cassette" is a "TFF membrane cassette" with a screen. See CureVac's Zydney Opp'n (ECF No. 549-22, at 10). Because CureVac never acknowledges that the plain and ordinary meaning of "TFF membrane cassettes" includes cassettes with or without screens, CureVac makes no attempt to "set forth a definition of the disputed claim term other than its plain and ordinary meaning." Similarly, CureVac makes no attempt to "express an intent to redefine the term" outside of its claim that Dr. Zydney merely applies what CureVac believes to be the plain and ordinary meaning of the phrase. Thus, to the extent Dr. Zydney was attempting to assert a lexicography argument, that argument fails.[3]

[3] As discussed above, CureVac simultaneously asserts that it has not waived its arguments concerning the meaning of "TFF membrane cassette," but also distances itself from Dr. Zydney's lexicographic argument. Accordingly, CureVac appears to draw a distinction between "arguments concerning the meaning of 'TFF membrane cassette'" and lexicographic claim construction. Regardless, neither CureVac, nor Dr. Zydney, can limit the phrase "TFF membrane cassette" to only cassettes with screens.

3. Dr. Zydney's Opinions Based on an Incorrect Understanding of the Claim are Excluded.

Expert testimony is admissible under Rule 702 only if it will aid the jury or other trier of fact to understand or resolve a fact at issue. Westberry, 178 F.3d at 260 (citing Daubert, 509 U.S. at 592). "[P]rior art cannot be distinguished on the ground that it lacks features that are not claim limitations," Melchior v. Hilite Int'l, Inc., 665 F. App'x 894, 899-900 (Fed. Cir. 2016) (collecting cases), and testimony based on "impermissible claim construction . . . could prejudice and confuse the jury," see, e.g., Liquid Dynamics Corp. v. Vaughan Co., Inc., 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006). Because the TFF Patents contemplate TFF membrane cassettes with or without screens, Dr. Zydney's expert testimony based on his artificially narrowed construction of the claim term "TFF membrane cassette" is irrelevant and likely to confuse the jury. Thus, Dr. Zydney's attempt to distinguish prior art on the basis that the prior art does not use a "TFF membrane cassette" with a screen is inadmissible. The court excludes any opinions by Dr. Zydney which depend on a construction of the claim term "TFF membrane cassette" that limits the meaning only to a "TFF membrane cassette with a screen," including paragraphs 72-75, 80-81, 180, 183, 190-91, 200-01, 272-75, 284, 290, 308, 320, 321-23, 328-29, 338, 349, 370, 437, 466-68, 503-06, 509, and 526 in Ex. G (ECF No. 441-6).

CureVac expresses concern that BioNTech requests that this court exclude opinions by Dr. Zydney discussing TFF membrane cassettes generally, without respect to whether the cassette has a screen. Upon review, it appears that Dr. Zydney primarily relies on the presence of screens to support his opinion that in 2015, a POSA would not have expected a TFF membrane cassette to properly filter shear-sensitive molecules. However, the court cannot discern whether, in every

sentence of sections VIII.D, VIII.E, or VIII.F, or paragraphs 235-37, 243-44, 404, and 424,[4] Dr. Zydney bases his opinions on his belief (not expressed in the claim term) that a membrane cassette inherently contains a screen. To the extent that Dr. Zydney seeks to distinguish a TFF membrane cassette from a spin filter or a hollow fiber membrane based on a feature of a membrane cassette other than the presence of a screen, Dr. Zydney may be permitted to do so. But, as stated above, the court finds any distinction made based on whether the TFF membrane cassette contained a screen irrelevant, and therefore, inadmissible. If BioNTech believes Dr. Zydney is distinguishing TFF membrane cassettes from spin filters or hollow fiber membrane devices based on the presence of a screen at trial, it should object to Dr. Zydney's testimony then.

B. CureVac Can Introduce or Discuss an Additional Section of BioNTech's Biologics License Application.

In BioNTech's Motion in Limine No. 6, (ECF No. 587), BioNTech argues that the court should preclude CureVac from introducing or discussing an additional section of BioNTech's Biologics License Application ("BLA") for Comirnaty®, cited for the first time by CureVac in its opposition to the Daubert motion seeking to exclude Dr. Zydney's testimony. Mem. Supp. BioNTech & Pfizer's Mot. Limine No. 6 ("BioNTech's No. 6 Mem.") (ECF No. 589, at 1) (sealed version); see also CureVac's Zydney Opp'n (ECF No. 549-22, at 2) (citing Ex. 4 (ECF No. 549-24) (sealed version)). BioNTech argues that Dr. Zydney "never looked to see if such a TFF filter with a 'screen' was used in the accused process" in his infringement analysis, failing to make the argument that BioNTech used commercially available membrane cassettes with screens. BioNTech's No. 6 Mem. (ECF No. 589, at 3). BioNTech also asserts that Dr. Rathore, BioNTech's

[4] BioNTech lists paragraph 423 in its motion in limine. However, that paragraph makes no specific mention of a screened membrane cassette. Upon review of paragraph 424, the court believes BioNTech meant to request exclusion of this paragraph, given Dr. Zydney's assertion that "The Moderna publication does not disclose performing a TFF unit operation to purify RNA with a membrane cassette." Ex. G (ECF No. 441-6, ¶ 424).

own expert on the TFF Patents, never addressed whether BioNTech used TFF membrane cassettes with screens in his opening report. Id. at 4. Therefore, the court should not permit CureVac to reference a document supporting a new argument outside the scope of the TFF expert reports. Id. at 4.

CureVac responds that Dr. Zydney does not intend to introduce any new infringement theories at trial, maintaining his opinion that BioNTech infringed the TFF Patents when it used TFF membrane cassettes to purify linearized DNA and mRNA. CureVac's Opp'n Defs.' Mot. Limine No. 6 ("CureVac's No. 6 Opp'n") (ECF No. 708-11, at 1) (sealed version). CureVac also contends that Dr. Rathore did not challenge Dr. Zydney's opinion that BioNTech used membrane cassettes. Id. Further, CureVac contends that until BioNTech challenged Dr. Zydney's opinions on the construction of the term "membrane cassette," CureVac had no reason to cite to BioNTech's documents showing they used membrane cassettes with screens to make Comirnaty®, substantially justifying the use of the document. Id. CureVac explains that the additional section of BioNTech's BLA it cites identifies the specific brand and model of membrane cassette BioNTech used. Id. at 2. Because BioNTech, in fact, used membrane cassettes with screens to make Comirnaty®, CureVac contends that BioNTech is not unfairly prejudiced by Dr. Zydney relying on this additional document. Id.

Excluding evidence for failure to timely disclose it as required by Rule 26(a) is a discovery sanction under Rule 37(c) within the court's discretion. S. States Rack & Fixture, Inc. v. Sherwin-Williams Co., 318 F.3d 592, 595 (4th Cir. 2003); see Fed. R. Civ. P. 26(a)(2)(B) (stating that an expert report must contain a complete statement of all opinions witness will express, facts or data witness considered, and any exhibits used to support expert's opinions). However, "Rule 37(c)(1) provides two exceptions to the general rule excluding evidence that a party seeks to offer but has

failed to properly disclose: (1) when the failure to disclose is 'substantial[ly] justifi[ed],' and (2) when the nondisclosure is 'harmless.'" Id. at 596 (alterations in original).

Courts in the Fourth Circuit generally address these two exceptions together by applying the five-factor test adopted in Southern States. See id. at 596-97; Zaklit v. Glob. Linguist Sols., LLC, No. 1:14-cv-314, 2014 WL 4925780, at *4 (E.D. Va. Sept. 30, 2014); Rambus, Inc. v. Infineon Techs. AG, 145 F. Supp. 2d 721, 726-27 (E.D. Va. 2001); Swimways Corp. & VAP Creative, LTD v. Zuru, Inc., No. 2:13-cv-334, 2014 WL 12573390, at *2-4 (E.D. Va. July 10, 2014). But the court is "not required to tick through each of the Southern States factors. Southern States explains that district courts have 'broad discretion' to decide harmlessness and 'should' – not 'shall' – 'be guided by' the five factors." Wilkins v. Montgomery, 751 F.3d 214, 222 (4th Cir. 2014). Those factors are:

> (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence.

S. States, 318 F.3d at 597.

Here, CureVac's nondisclosure is harmless, and BioNTech will not be unduly prejudiced by the late disclosure of and reliance on the document. The BLA in question is BioNTech's own document. The section of the BLA cited by CureVac identifies the brand and model of TFF membrane cassette used in one step of manufacturing Comirnaty®, and BioNTech cannot dispute—and has not disputed—that it used TFF membrane cassettes with screens to make Comirnaty®. Further, before BioNTech filed the present motion in limine, CureVac added the document to its exhibit list. Given the limitations imposed by the court above, and because

BioNTech cannot claim surprise from the contents of its own document, CureVac can introduce and rely on "BIONTECH_COMIR 00111451."[5] See Ex. 4 (ECF No. 549-24).

C. Dr. Rathore's Opinions are Sufficiently Reliable and Relevant Under the Federal Rules of Evidence.

In CureVac's Motion to Exclude Expert Testimony of Anurag S. Rathore, Ph.D., (ECF No. 503), CureVac argues that the court should exclude the testimony of Dr. Rathore on the issue of obviousness because he fails to identify any combination of prior art references to support his opinions. CureVac's Rathore Mem. (ECF No. 491-31, at 1). Specifically, CureVac takes issue with the fact that Dr. Rathore "attempts to combine each of the same prior-art references on which he relies to support his flawed anticipation theories with 'all' of the prior-art references that would have been known to a POSA at the relevant time," or, in other words, the general knowledge of a POSA. Id. at 7. CureVac cites DSS Technology Management, Inc. v. Apple Inc., 885 F.3d 1367 (Fed. Cir. 2018), to argue that Dr. Rathore must reference "the missing limitation" of the cited prior art in another prior art reference to prove obviousness, and that Dr. Rathore is prohibited from using the general knowledge of a POSA as a "gap-filler to supply a missing limitation." CureVac's Rathore Mem. (ECF No. 491-31, at 8) (internal quotation marks omitted). CureVac claims that under DSS, general knowledge can only be used to combine existing ideas; general knowledge can "only fill in a missing part of the invention where that part is 'unusually simple and the technology is particularly straightforward[;]'" and general knowledge cannot be used as a

[5] CureVac asserts in its opposition that Dr. Zydney does not seek to introduce any new infringement theories at trial. CureVac's No. 6 Opp'n (ECF No. 708-11, at 1, 4). Presumably, Dr. Zydney did not specify in his infringement opinion that the TFF membrane cassette included a screen because of his view that the presence of a screen was presumed by the ordinary language of the claim term. Having won the argument that it is not, BioNTech should not be prejudiced in having to defend its use of a membrane cassette. BioNTech should object to Dr. Zydney's testimony about the additional section of the BLA if it is used to introduce a new infringement theory or in attempts to distinguish prior art based on whether the TFF membrane cassette contains a screen.

wholesale substitute for an expert's analysis and evidentiary support. Id. (quoting 885 F.3d at 1374).

CureVac also argues that the court should exclude Dr. Rathore's testimony on noninfringing alternatives, specifically his opinion that BioNTech could have adopted the use of hollow fiber filters in "less than two months" with "trivial costs associated." Id. at 1-2, 9. CureVac argues that because Dr. Rathore "failed to provide analysis demonstrating how his short list of supporting assertions actually relates to transitioning from TFF cassettes to hollow fiber," his opinion is "ipse dixit without appropriate foundation." Id. at 11.

BioNTech responded, claiming that Dr. Rathore's obviousness opinions properly apply the law under KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007). BioNTech's Rathore Opp'n (ECF No. 544, at 1). BioNTech asserts that under KSR, Dr. Rathore "established that the CureVac TFF Patents simply arranged known elements (i.e., a TFF membrane cassette) to perform the same function they were known to perform (i.e., filtering biomolecules including nucleic acids) and to yield no more than a POSA would reasonably expect from such an arrangement." Id. at 10. BioNTech points to several instances in which Dr. Rathore "used documented evidence of a POSA's knowledge to demonstrate the motivation to have used a TFF membrane cassette," claiming that Dr. Rathore properly supported his opinions. Id. at 10-13. BioNTech asserts that "Dr. Rathore did not use general knowledge of a POSA to fill a limitation of the asserted claims missing from the prior art," explaining that TFF membrane cassettes are disclosed and promoted in the published prior art. Id. at 15.

BioNTech also argues that Dr. Rathore supported his opinions on noninfringing alternatives with sufficient evidence and analysis, pointing to his experience in the biopharmaceutical industry, his specialized knowledge on manufacturing processes, his citation to

sworn testimony of those involved in manufacturing Comirnaty®, his reliance on documents demonstrating BioNTech's manufacturing processes, and his reference to other commercial sale processes. Id. at 18-25.

CureVac replied, contending that the prior art references identified by Dr. Rathore, specifically WO '027 and WO '773, fail to identify any TFF configuration. CureVac's Reply Mem. Supp. Mot. Exclude Test. of Anurag S. Rathore, Ph.D. ("CureVac's Rathore Reply") (ECF No. 670, at 2-3). CureVac also points to other sources in its reply that weaken Dr. Rathore's opinion on noninfringing alternatives and again argue that Dr. Rathore fails to connect the evidence he provides to the issue of transitioning to the use of TFF hollow fiber filtration in manufacturing Comirnaty®. Id. at 8-10.

1. Dr. Rathore's Obviousness Opinions.

The text of Rule 702 explicitly contemplates experiential experts. Fed. R. Evid. 702 (listing "experience" as an expert qualification"); see also Fed. R. Evid. 702 advisory committee's note ("Nothing in this amendment is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony."). "Purely scientific testimony . . . is characterized by 'its falsifiability, or refutability, or testability.'" Wilson, 484 F.3d at 274 (quoting Daubert, 509 U.S. at 593). But experiential expert testimony does not "rely on anything like a scientific method," causing the district court's role in "examining the reliability of experiential expert testimony" to become "somewhat more opaque." Id. (citing Fed. R. Evid. 702 advisory committee's note). Nevertheless, the court's gatekeeping role "is to 'make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" Cooper, 259 F.3d at 200 (citing Kumho Tire, Co., 526 U.S. at 152). Therefore,

courts must still require an experiential expert to "explain how [his] experience leads to the conclusion reached, why [his] experience is a sufficient basis for the opinion, and how [his] experience is reliably applied to the facts." Wilson, 484 F.3d at 274 (quoting Fed. R. Evid. 702 advisory committee's note) (alterations in original).

"A patent claim is invalid as obvious when the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103. The United States Supreme Court in KSR broadly criticized the rigid approach to obviousness "based on the disclosures of individual prior-art references, with little recourse to the knowledge, creativity, and common sense that an ordinarily skilled artisan would have brought to bear when considering combinations or modifications." Randall Mfg. v. Rea, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (citing KSR Int'l Co., 550 U.S. at 406). In KSR, the Court recognized that a court will often look to "the background knowledge possessed by a person having ordinary skill in the art" to determine obviousness. 550 U.S. at 418. This flexible approach is consistent with other decisions suggesting that the obviousness inquiry "not only permits, but requires, consideration of common knowledge and common sense." Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1367 (Fed. Cir. 2006); see also Koninklijke Philips N.V. v. Google LLC, 948 F.3d 1330, 1338 (Fed. Cir. 2020) (affirming obviousness when "the claims would have been obvious over SMIL 1.0 in light of the general knowledge of a skilled artisan."); B/E Aerospace, Inc. v. C&D Zodiac, Inc., 962 F.3d 1373, 1380 (Fed. Cir. 2020) (affirming obviousness when "invocation of common sense was properly accompanied by reasoned analysis and evidentiary support," even when supplying a missing claim limitation with common sense).

While courts must "consider common sense, common wisdom, and common knowledge in analyzing obviousness," common sense cannot be used as a "wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified." Arendi S.A.R.L. v. Apple Inc., 832 F.3d 1355, 1361-62 (Fed. Cir. 2016). Further, invoking common sense to supply a missing limitation should typically only occur when "the limitation in question was unusually simple and the technology particularly straightforward." Id. at 1362 (citing Perfect Web Techs., Inc. v. InfoUSA, Inc., 587 F.3d 1324 (Fed. Cir. 2009); see also DSS, 885 F.3d at 1374-75.[6]

Here, Dr. Rathore invoked the general knowledge of a POSA accompanied by reasoned analysis and evidentiary support, rendering his obviousness opinion reliable. Dr. Rathore provides a nine-page overview of "The State of the Art as of May 2015," cross referencing prior art he discussed in other sections of his report and discussing how the prior art informed the general knowledge of a POSA at the time CureVac filed the TFF Patents. See Ex. 3 (ECF No. 491-32, ¶¶ 202-12, 381). In this overview, he explains that a POSA would have been aware that many companies commercially sold TFF devices—including TFF membrane cassettes—and promoted them in biopharmaceutical applications. Id. ¶¶ 203-04, 209-10. Later in his report, Dr. Rathore combines the generalized knowledge of a POSA with specific prior art references—Moderna WO '027, Shire WO '773, and the GSK '139 publication—in analyzing the motivation to use a TFF membrane cassette. See generally id. §§ X.B-C, XII.B-D; see, e.g., ¶ 222 ("WO '027 provided the motivation for a POSA to use a TFF membrane cassette. For example, WO '027 discloses

[6] While these cases determine the types of evidence and level of analysis required for a finding of obviousness supported by substantial evidence, admittedly none of the above cases—or the cases provided in the briefing—evaluate whether an expert's use of "generalized knowledge" in an obviousness analysis requires exclusion under Daubert or Rule 702. Nonetheless, evaluating whether Dr. Rathore properly used "generalized knowledge" under KSR reveals whether his testimony will ultimately be helpful to the trier of fact at trial in determining the issue of obviousness.

methods for production of mRNA that use 'linearized DNA template' for purposes of '[s]calability' and '[l]arge scale production.' TFF membrane cassettes were known to be the '[e]xcellent' choice for achieving scalability in connection with various filtration needs, and were 'the obvious choice' for 'linear scaling.'"). His detailed analysis and thorough citations, accompanied by his extensive background in the field of biopharmaceuticals, adequately supports his opinions under Daubert and Rule 702.

CureVac relies on DSS to argue that Dr. Rathore uses "generalized knowledge" as a gap-filler in his analysis. However, in DSS, the Board explained its finding of obviousness in a single paragraph, substituting any cite to the record for a reliance on "ordinary creativity" to explain why a POSA would have been motivated to "modify Natarajan to incorporate such a technique into a base unit transmitter." 885 F.3d at 1375. Unlike the Board's conclusory decision in DSS, Dr. Rathore paired his use of generalized knowledge with prior art and thorough explanation, far from a "wholesale substitute for reasoned analysis and evidentiary support." See id.; see also Arendi, 832 F.3d at 1362. Moreover, the court in DSS reviewed the Patent Trial and Appeal Boards' findings of obviousness, rather than determining whether an expert used reliable principles and methods under Daubert or Rule 702. DSS, 885 F.3d at 1374. Dr. Rathore's methods meet the Daubert standard for admissibility, and CureVac's insistence that "generalized knowledge" cannot support a finding of obviousness is an argument regarding the weight of his testimony, not a basis to exclude it.

Dr. Rathore's detailed expert report uses accepted types of evidence under KSR to provide his analysis, rendering his opinion helpful to the jury in determining obviousness. Thus, because Dr. Rathore bases his opinion on sufficient facts and data, the court finds that his obviousness opinions are both reliable and relevant.

2. Sufficient Evidence and Substantial Expertise Supports Dr. Rathore's Noninfringing Alternatives Opinions.

As mentioned above, Daubert and Rule 702 only require a court to exclude expert testimony if the expert's reasoning or methodology is unreliable and if the opinion is irrelevant to the facts at issue. See 509 U.S. at 592. In other words, "a reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." Oglesby, 190 F.3d at 250 (citing Daubert, 509 U.S. at 590, 592-93).

Moreover, the text of Rule 702 contemplates testimony based on experience. Fed. R. Evid. 702 (listing "experience" as an expert qualification"); see also Fed. R. Evid. 702 advisory committee's note ("Nothing in this amendment is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony."). When opining based on his experience, Dr. Rathore is not required to "'rely on anything like a scientific method.'" Wilson, 484 F.3d at 274 (quoting Fed. R. Evid. 702 advisory committee's note). Rather, the question is whether Dr. Rathore can "explain how [his] experience leads to the conclusion reached, why [his] experience is a sufficient basis for the opinion, and how [his] experience is reliably applied to the facts." Id. (quoting Fed. R. Evid. 702 advisory committee's note) (alterations in original); see also Cooper, 259 F.3d at 199-200 (quoting Kumho Tire Co., 526 U.S. at 150, 152).

Here, Dr. Rathore combined his experience in the industry, his scientific and specialized knowledge, and documentary evidence to support his analysis on noninfringing alternatives. In addition to his own experience, Dr. Rathore relied on various types of evidence in his report, including technical information generated by BioNTech's research and development of Comirnaty® and FDA submissions for approval to test and sell the vaccine. Ex. 4 (ECF No. 491-

33, ¶¶ 64-65, 67). He also relied on his familiarity with commercial-scale TFF using hollow fiber and on BioNTech's experience actually implementing TFF hollow fiber for purification of Comirnaty® in the manufacturing process, rebutting Dr. Zydney's claim that BioNTech could not achieve regulatory approval to implement TFF hollow fiber. Id. ¶ 65 (citing Zydney Ex. 15 (ECF No. 491-34 (PFI_CUR_00117434 at -7440)). Dr. Rathore also relied on sworn deposition testimony by Dr. Andreas Kuhn, BioNTech's head of manufacturing, and Dr. Ranga Godavarti, Pfizer's Vice President of Bioprocess Research and Development to support his opinion. Id. at ¶ 67. Further, Dr. Rathore relies on his own experience in the biopharmaceutical industry scaling up using TFF and gaining regulatory approval. See, e.g., Ex. 1 (ECF No. 545-1, 73:3-11). Dr. Rathore has worked on the manufacturing process of over fifty biopharmaceuticals, ten of which gained FDA approval. See id. 24:22-25:4, 27:5-11. Given Dr. Rathore's reliance on documentary evidence, articles, and his own experience, the reasoning underlying his proffered opinion is reliable, and his opinion as to noninfringing alternatives is relevant to the facts at issue.

As with its earlier arguments, CureVac seems to primarily focus on the weight—rather than admissibility—of Dr. Rathore's arguments. While CureVac points to evidence that conflicts with Dr. Rathore's opinion, this conflict in evidence does not require the court to exclude Dr. Rathore's opinion. Instead, CureVac can use such evidence to cross-examine Dr. Rathore. This court agrees that CureVac's challenge to Dr. Rathore's testimony on noninfringing alternatives merely highlights a factual dispute between TFF experts regarding the viability of TFF hollow fiber, which does not serve as a basis for exclusion. Because Dr. Rathore properly invokes his experience and relies on documentary evidence to support his opinion on noninfringing alternatives, Dr. Rathore's testimony is both reliable and relevant.

IV. CONCLUSION

For the foregoing reasons, and subject to the limitations expressed in this Opinion, the court GRANTS BioNTech's Motion to Exclude Testimony from Dr. Zydney, (ECF No. 470), GRANTS BioNTech's Motion in Limine No. 13, (ECF No. 608), DENIES BioNTech's Motion in Limine No. 6, (ECF No. 587), and DENIES CureVac's Motion to Exclude Testimony from Dr. Rathore, (ECF No. 503).

IT IS SO ORDERED.

/s/
Douglas E. Miller
United States Magistrate Judge

DOUGLAS E. MILLER
UNITED STATES MAGISTRATE JUDGE

Norfolk, Virginia
February 14, 2025